

REMARKS/ARGUMENTS

Claims 10-12 are pending in the application. Claims 10-11 are allowed. Claim 12 stands rejected. Claim 12 has been amended. Claim 27 has been added. Entry of the amendment, reconsideration of the rejection, and allowance of claims 10-12 and 27 are requested.

The Amendment

In order to expedite prosecution of the application and advance the case toward allowance, claim 12 has been amended. No new matter was added by the amendment.

Claim 12 has been amended to specify that SGT is selectively eluted from the immobilized affinity moiety with an eluant comprising arginine. Support for this amendment can be found on page 8, paragraph [029], lines 4-7; and page 9, paragraph [031], lines 1-3, and paragraph [032], line 1.

New claim 27 depends on claim 12 and specifies that the immobilized affinity moiety is benzamidine. Support for this amendment can be found on page 6, paragraph [022] and page 19, paragraph [071].

Specification and Claim Objections

Applicants gratefully acknowledge that the prior objections have been withdrawn.

Rejections under 35 U.S.C. §112

Claim 12 is newly rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for the claimed composition obtained by contacting a PRONASE protease preparation with immobilized benzamidine and then eluted therefrom with arginine, is allegedly not enabled for such compositions wherein each of the immobilized affinity moiety and the eluting moiety is selected from any of an amidine, a guanidine, and an amine containing species.

To the extent that the rejection applies to claim 12 as amended, Applicants respectfully traverse the rejection.

The office action indicates that the claims cover SGT compositions having a specific activity of at least about 25×10^3 U/mg and a purity of at least 95%, and that the specification recites that *immobilization with benzamidine* and *elution with arginine* results in a SGT composition with the claimed specific activity and purity. Further, the office action indicates that an example demonstrates that *immobilization and elution with benzamidine* results in SGT compositions with a specific activity of only 19×10^3 U/mg. The Examiner then concludes that only certain combinations of the indicated immobilization and elution moieties are capable of achieving the claimed compositions.

Claim 12 has been amended to specify that SGT is selectively eluted from the immobilized affinity moiety with an eluant comprising arginine. However, the amendment was made to advance the claims toward allowance and must not be construed as an acquiescence in the rejection. It is further stated for the record that it would be unduly limiting to restrict the claim to *immobilization with benzamidine*, particularly in light of the teachings on pages 6-7, particularly paragraphs [022], [023], and [024] of the specification. Therein, the Applicants teach in great detail what types of immobilized affinity moieties (*i.e.*, amidine, guanidine, amine-containing species) can be used in this invention. Armed with this knowledge the skilled artisan can easily employ a suitable moiety. Although the immobilization procedure is exemplified via use of benzamidine, it is not limited to the use of benzamidine. If the Applicants are restricted to only benzamidine, the Applicants may be faced with a situation where benzamidine is no longer commercially available which would place an undue burden on the Applicants. Not to mention, that others would be encouraged to infringe upon the Applicants' invention by simply employing a slightly different moiety.

It is the Examiner's burden to explain by reason or evidence why other immobilized affinity moieties, such as the ones discussed in the specification, would not work in light of the instant teaching that they do work. In fact, the specification teaches several types of immobilized affinity moieties (*e.g.*, **amidines** such as benzamidine hydrochloride; p-aminobenzamidine dihydrochloride; APMSF hydrochloride; 4- amidinophenylmethanesulfonyl - fluoride HCl; bis(5-amidino-2-benzimidazolyl)methane; a,a'-bis (4-amidino-2-iodophenyl)-p-xylene; 1,2-bis(5-amidino-2-benzofuranyl)ethane; and 6-amidino-2-(4-amidinophenyl)benzo-

[β]thiophene; **guanidines** such as guanidinoacetic acid and derivatives; substituted or unsubstituted guanidinobenzoic acids; and arginine and analogues; and **amine-containing species** such as amino acids and amino acid analogues, including lysine and ε-amino caproic acid) on pages 6-7 (*supra*). Thus, if the Applicants were to use an immobilized affinity moiety such as an amidine, guanidine, or an amine-containing species in combination with arginine as eluting moiety, there is no reason to assume that the Applicants would not achieve the desired preparation of SGT in the absence of evidence to the contrary. In addition, newly added claim 27 depends on claim 12 and specifies that the immobilized affinity moiety is benzamidine.

In light of the above amendment and remarks, Applicants respectfully request that the rejection of claim 12 under 35 U.S.C. §112, first paragraph, be withdrawn.

Rejections under 35 U.S.C. §102

Claims 10 and 12 were rejected under 35 U.S.C. §102(b) as being anticipated by Koo *et al.* Applicants gratefully acknowledge that the rejection was withdrawn with respect to claim 10. Claim 12 remains rejected because it does not require the presence of the arginine eluant.

Claim 12 has been amended to require the presence of the arginine eluant, hence, this rejection should be withdrawn.

Rejections under 35 U.S.C. §103

Claim 11 was rejected under 35 U.S.C. §103(a) as being unpatentable over Koo *et al.* in view of Kasai. Applicants gratefully acknowledge that the rejection was withdrawn.

CONCLUSION

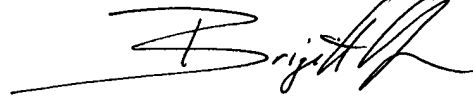
In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Appl. No. 10/006,223
Amdt. dated April 8, 2004
Reply to Office Action of January 15, 2004

PATENT

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Brigitte A. Hajos', with a long horizontal line extending to the left.

Brigitte A. Hajos
Reg. No. 50,971

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 650-326-2400
Fax: 415-576-0300
Attachments
BAH:bah
60133305 v1